

UNITED STATES DISTRICT COURT
for the
District of Massachusetts

In re NECC Products Liability Litigation (MDL)

Plaintiff

v.

This document relates to all suits
against the Saint Thomas Entities

Defendant

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)
)
)
)

Civil Action No. MDL No. 2419; 1:13-md-2419

**SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS
OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION**

To:

Alaunus Pharmaceutical, LLC

(Name of person to whom this subpoena is directed)

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached discovery requests.

Place: Nutter McClennen & Fish LLP 155 Seaport Blvd Boston, MA 02210	Date and Time: 04/13/2015 10:00 am
--	---------------------------------------

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:
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The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 03/09/2015

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing (name of party) _____
the Saint Thomas Entities _____, who issues or requests this subpoena, are:

Sarah Kelly, NUTTER McCLENNEN & FISH, 155 Seaport Blvd, Boston, MA 02210, skelly@nutter.com, 617-439-2000

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. MDL No. 2419; 1:13-md-2419

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for (*name of individual and title, if any*) _____

on (*date*) _____ .

I served the subpoena by delivering a copy to the named person as follows: _____

on (*date*) _____ ; or

I returned the subpoena unexecuted because: _____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of

\$ _____ .

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) For Other Discovery. A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
<hr/>		
THIS DOCUMENT RELATES TO:)	MDL No. 2419
		Dkt. No 1:13-md-2419 (RWZ)
All Suits Against the Saint Thomas Entities)	
)

**SAINT THOMAS ENTITIES' REQUESTS FOR PRODUCTION TO
ALAUNUS PHARMACEUTICAL, LLC**

Come the Defendants, Saint Thomas West Hospital f/k/a St. Thomas Hospital; Saint Thomas Health; and Saint Thomas Network (collectively the “Saint Thomas Entities”), and submit the following Requests for Production to Alaunus Pharmaceutical, LLC.

II. DEFINITIONS

- A. As used herein, “Alaunus,” “you,” and “your” refer to Alaunus Pharmaceutical, LLC, a Massachusetts limited liability company with its principal offices located at 687 Waverly Street, Framingham, Massachusetts 01702, and each of its present and former owners, managers, agents, representatives, contractors, employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- B. As used herein, “NECC” refers to New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center, with its principal place of business located at 697 Waverly Street, Framingham, Massachusetts 01702, and each of its present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- C. As used herein, the term “Lawsuit” refers to all lawsuits involved in *In re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 2419, Dkt. No. 1:13-md-2419, pending in the United States District Court for the District of Massachusetts.
- D. As used herein, “Plaintiff” and “Plaintiffs” refer to the Plaintiffs in this Lawsuit who have pending and active cases, as well as their agents, heirs, personal representatives, and assigns, and each person acting or purporting to act on his/her/their behalf.

- E. As used herein, "Ameridose" refers to Ameridose, LLC, a Massachusetts limited liability company with its principal offices located at 205 Flanders Road, Westborough, Massachusetts 01581, and each of its present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- F. As used herein, "Liberty," refers to Liberty Industries, Inc., a Connecticut corporation with its principal place of business at 133 Commerce Street, East Berlin, Connecticut 06023, and each of its present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- G. As used herein, "ARL" refers to ARL BioPharma, Inc. d/b/a Analytical Research Laboratories, an Oklahoma corporation with a principal place of business located at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104, and each of its present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- H. As used herein, "UniFirst," and "UniClean" refer to UniFirst Corporation d/b/a UniClean Cleanroom Services, a corporation duly organized and existing under and by virtue of the laws of the State of Massachusetts, with its principal place of business located at 68 Jonspin Road, Wilmington, Massachusetts 01887, and each of its present and former owners, managers, agents, representatives, contractors, employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- I. As used herein, "Victory" refers to Victory Heating & Air Conditioning Co. Inc./Victory Mechanical Services, Inc., Massachusetts corporations with their principal offices located at 115 Mendon St., Bellingham, Massachusetts 02019, and each of their present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- J. As used herein, "MSM" refers to Medical Sales Management Inc., a Massachusetts corporation with a principal place of business located at 701 Waverly Street, Framingham, Massachusetts 01702, and each of its present and former owners, managers, agents, representatives, contractors, employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- K. As used herein, "GDC" refers to GDC Properties Management, LLC, a Massachusetts limited liability company with its principal offices located at 701 Waverly Street, Framingham, Massachusetts 01702, and each of its present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- L. As used herein, "FDA" refers to the United States Food and Drug Administration.
- M. As used herein, "MBP" refers to the Massachusetts Board of Registration in Pharmacy.

N. As used herein, “NECC facility” refers to the facility located on Waverly Street, Framingham, Massachusetts 01702, where compounding of the pharmaceuticals at issue in this Lawsuit occurred.

O. As used herein, the term “MPA” means methylprednisolone acetate.

P. As used herein, “USP” refers to United States Pharmacopeia, a nonprofit private group that develops standards of drug quality. “USP” followed by a chapter or section number refers to the indicated chapter or section of USP standards and/or tests.

Q. As used herein, “NECC cleanrooms” refers to the cleanrooms at the NECC facility.

For each Request or Interrogatory that seeks information about the NECC cleanrooms, please respond with respect to each cleanroom that you had any role whatsoever in procuring products or services for, or in which you or any of your employees compounded, manufactured, or tested MPA.

R. As used herein, the term “communication” includes, without limitation, every manner or means of statement, utterance, notation, disclaimer, transfer, or exchange of information of any nature whatsoever, by or to whomever, whether oral, written, or face-to-face, by telephone, U.S. mail or other delivery service, facsimile, personal delivery, electronic mail, computer, or otherwise, specifically including, without limitation, correspondence, conversations, dialogue, discussions, interviews, consultations, agreements, and other understandings.

S. As used herein, the term “document” means any writing and other tangible thing in the custody, possession or control, or which was, but is no longer in the possession, custody, or control, of the answering party or known to the answering party—whether printed, recorded, reproduced by any process, or written or produced by hand, and whether or not claimed to be privileged or exempt from production for any reason—including, but not limited to, letters, reports, agreements, all official and personal communication, correspondence, telegraphs, memoranda, summaries, computer files or other electronic media, e-mails, records of personal conversations, formal or informal notes, diaries, forecasts, photographs, tape recordings, charts, plans, drawings, minutes or recordings of conferences, expressions or statements of policy, lists of persons attending meetings or conferences, summaries of interviews, reports and/or summaries of investigations, opinions or reports of records, and drafts of any documents, including original or preliminary drafts and subsequently revised versions. Any comment or notation appearing on any document, and not part of the original text, is to be considered a separate “document.” Requests for a “document” specifically includes electronic or magnetic data.

T. As used in this document, the terms “identification,” “identify,” or “identity,” when used in reference:

- to a person, means to state his or her full name and present or last known residential address and phone number;

- b. to a firm, company, business, trust, corporation, partnership, association, governmental agency, governmental unit, or other organization and/or entity, means to state its full name and present or last known business address and phone number;
- c. to a statement and/or admission, means to identify who made it, who took or recorded it, and all others, if any, present during the making thereof; to state when, where and how it was taken or recorded, and to identify who has present possession custody or control thereof and/or who last had possession, custody, or control thereof;
- d. to tangible things, recordings, photographs, videotapes, motion pictures, x-rays, and/or radiographic films means to give a reasonably detailed description thereof, including, if applicable, when, where, and how made; to identify who made it, and who has present possession, custody or control thereof, and/or who last had possession, custody or control thereof; and
- e. to any documents, writings, and/or recordings means to set forth where the document exists, the date of authorship, the name of the author(s), a reasonably detailed description of its contents and all attachments to the original document, and the number of pages in the document and all attachments to the original document, and who has present possession, custody or control thereof, and/or who last had possession, custody or control thereof.

- U. As used herein, the terms “concerning,” “refer or relate,” or “referring or relating” mean, without limitation, referring to, relating to, having any relationship to, pertaining to, evidencing or constituting evidence of, originated by, representing, memorializing, summarizing, describing, discussing, analyzing, evaluating, directly or indirectly, or in whole or in part, the subject matter of the particular request.
- V. As used in herein, the term “person” includes any individual, natural person, partnership, association, organization, corporation, company, joint venture, firm, proprietorship, trust, estate, agency, board, authority, commission, or other legal or business entity of any kind.
- W. The singular includes the plural number, and vice versa. The masculine includes the feminine and neutral gender. The past tense includes the present tense where the clear meaning is not distorted by change of tense.
- X. The term “any” should be construed to include the word “all,” and “all” should be construed to include “any.”
- Y. The terms “and,” “or,” and “and/or” should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

REQUESTS FOR PRODUCTION

REQUEST FOR PRODUCTION NO. 1: The organizational charts for Alaunus that applied at any time from 2009 to 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 2: Documents sufficient to establish the ownership of Alaunus from 2009 to 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 3: Documents sufficient to establish the identity of each member of management at Alaunus from 2009 to 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 4: All documents referring or relating to the commingling of financial accounts between Alaunus, Ameridose and/or NECC.

RESPONSE:

REQUEST FOR PRODUCTION NO. 5: All proposals, bids, contracts and any other document containing or reflecting the terms and conditions pursuant to which you provided services related to compounding, repackaging, wholesaling, or distributing medication for NECC or Ameridose.

RESPONSE:

REQUEST FOR PRODUCTION NO. 6: All documents referring or relating to problems, inadequacies, contamination, air pressure concerns with the NECC cleanrooms.

RESPONSE:

REQUEST FOR PRODUCTION NO. 7: If you compounded, manufactured, distributed or repackaged MPA from 2009 to 2012, documents sufficient to establish each such activity.

RESPONSE:

REQUEST FOR PRODUCTION NO. 8: All documents referring or relating to the use of expired or expiring ingredients in any product compounded, repackaged, wholesaled, or distributed by Alaunus.

RESPONSE:

REQUEST FOR PRODUCTION NO. 9: With respect to the Wholesaler Inspection Report attached hereto as Exhibit "B," all versions of the following documents.

- a. The list of all officers, directors, managers and employees listing each of their positions/duties.
- b. The following written policies and procedures on prescription drugs: procedure requiring oldest stock to be distributed first; procedure on recall/withdrawal, and procedure to assure outdated drugs are separated or disposed of.

RESPONSE:

REQUEST FOR PRODUCTION NO. 10: All documents referring or relating to warnings you received from any regulatory authority, including without limitation the FDA or MBP, from 2009 to 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 11: All documents referring or relating to the reason you ceased doing business and shut down after MPA compounded by NECC was discovered to be contaminated in September 2012.

RESPONSE:

REQUEST FOR PRODUCTION NO. 12: All documents referring or relating to concerns or complaints about the NECC facility.

RESPONSE:

REQUEST FOR PRODUCTION NO. 13: All documents referring or relating to problems or concerns regarding the cleaning services provided by UniFirst to any clean room.

RESPONSE:

REQUEST FOR PRODUCTION NO. 14: All documents referring or relating to problems or concerns regarding the testing services provided by ARL for any compounded product.

RESPONSE:

REQUEST FOR PRODUCTION NO. 15: All documents referring or relating to the relationship between Alaunus and either Ameridose or NECC, including without limitation joint marketing efforts, joint e-mail and computer systems, sharing or employees or management, and sharing of office space or clean rooms.

RESPONSE:

REQUEST FOR PRODUCTION NO. 16: The corporate charter, bylaws and minutes from all board meetings that occurred, if any.

RESPONSE:

REQUEST FOR PRODUCTION NO. 17: All documents referring or relating to whether a particular customer, order, client, or product should be compounded, filled, processed, assigned or sold by and/or through Alaunus as opposed to Ameridose or NECC.

RESPONSE:

REQUEST FOR PRODUCTION NO. 18: Every page of your website as it existed at any point from 2009 to 2012.

RESPONSE:

Dated: March 9, 2015

By their attorneys,

/s/ Sarah P. Kelly

Sarah P. Kelly (BBO #664267)
skelly@nutter.com

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(512) 482-9300
(512) 482-9303

*Appearing Pro Hac Vice

CERTIFICATE OF SERVICE

I certify that the foregoing document was served in the following manner on the 9th day of March, 2015.

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Via Electronic Mail

Via U.S. Mail and Electronic Mail

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Via Electronic Mail

Via Electronic Mail

/s/ *Sarah P. Kelly*
Sarah P. Kelly

Exhibit A

2/18/2016

To: James Emery

From: Patrick Foster

Company: Alaurus Pharma Central

RE: Alaurus Inspection Follow-up Items

James,

The requested Clean Room Corrections

for our clean rooms

Patrick

S
A
A

Scientific Air Analysis, Inc.

47 Fatima Drive
 Ashland, MA 01721
 (508) 881-7100
 (508) 881-7105 FAX
 1-800-287-5252 MA ONLY

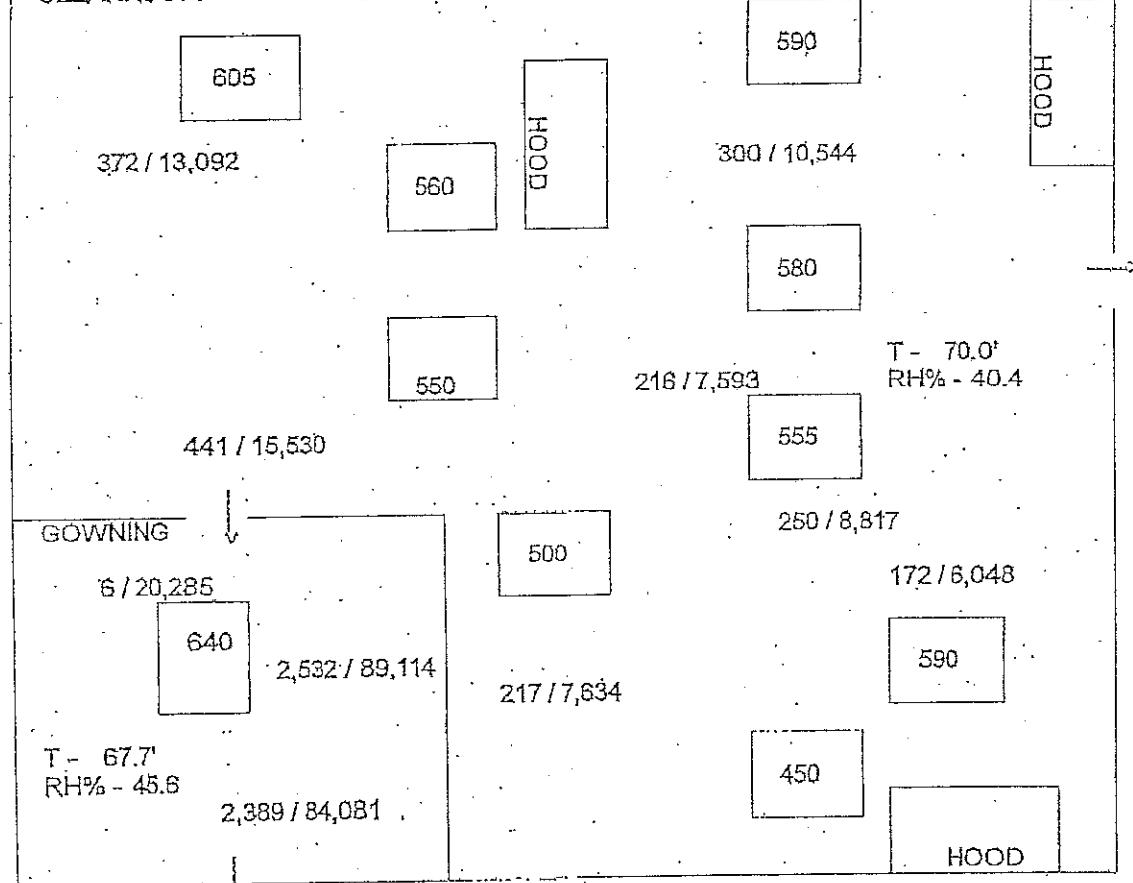
CLEANROOM #3 CERTIFICATION REPORT:

PARTICLE COUNTS
 PRESSURE DIFFERENTIALS

AIRFLOW PROFILES
 AIR CHANGES / HOUR

TEMPERATURE & REL. HUMIDITY

CLEANROOM CUBIC FEET / CUBIC METERS



ALAUNUS
 50 FOUNTAIN STREET
 FRAMINGHAM, MA 01702

TESTING DATE: 9-15-09

PARTICLES MEASURED AND RECORDED AT .5 MICRON SIZE IN CUBIC FEET AND CUBIC METERS
 OF AIR IN ACCORDANCE WITH ISO 14644-1.

	CLEANROOM	GOWNING
ROOM VOLUME:	3,738 FT3	600 FT3
TOTAL CFM:	6,010	640
AIR CHGS / HR:	80	64

PRESSURE DIFFERENTIALS:	CLEANROOM > GOWNING -	.110 POS
	GOWNING > OUTSIDE -	.091 POS
	CLEANROOM > OUTSIDE -	.201 POS

CLEANROOM CERTIFIED AS ISO CLASS 6. GOWNING CERTIFIED AS ISO CLASS 7.
 CLASS 6 LIMITS: CUBIC FEET - 1,000 / CUBIC METERS - 35,200
 CLASS 7 LIMITS: CUBIC FEET - 10,000 / CUBIC METERS - 352,000
 ALL TESTING WAS PERFORMED WITH THE CLEANROOM AT REST.

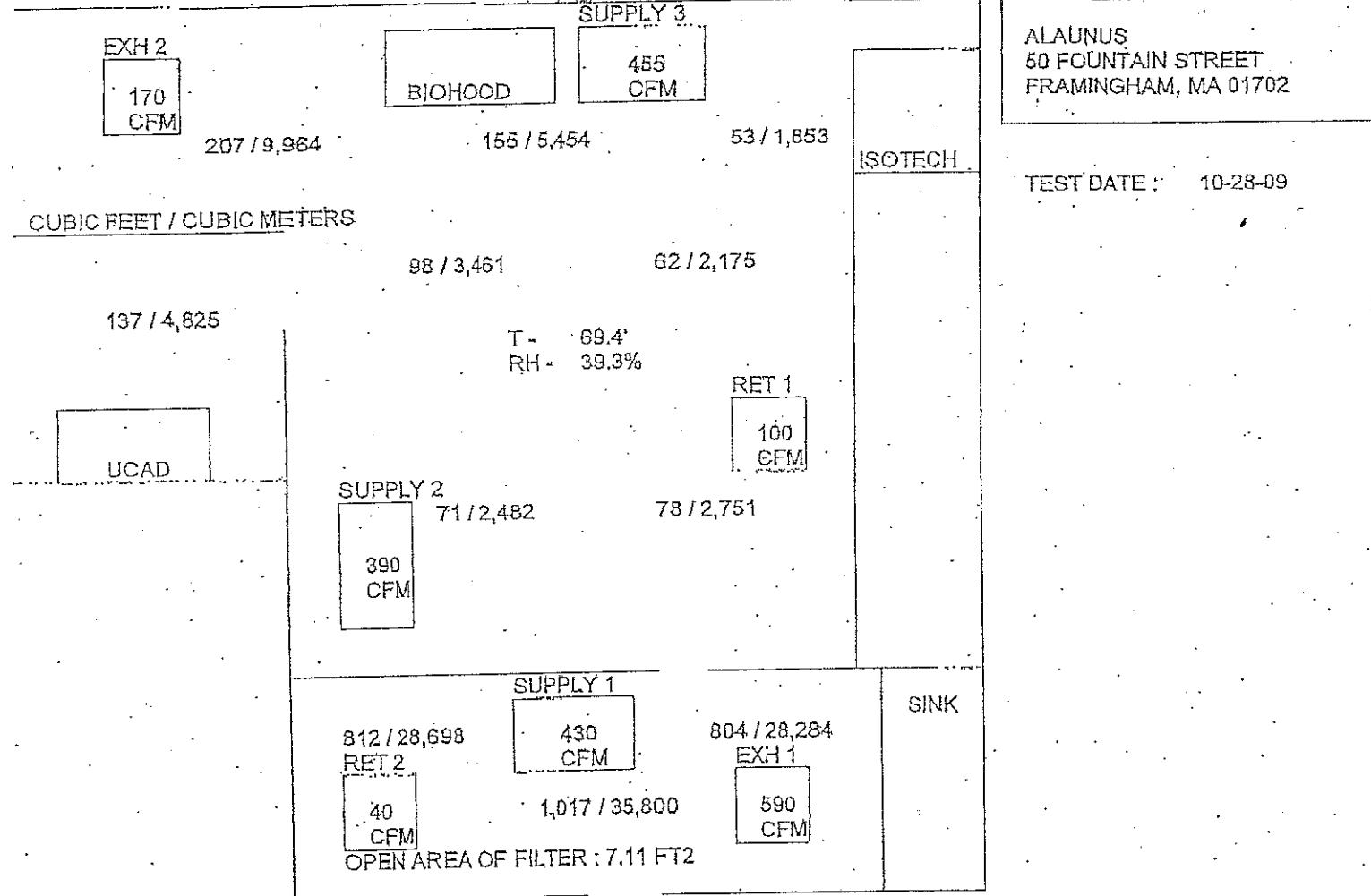
TECHNICIAN: 

S
A
A

Scientific Air Analysis, Inc.

47 Fatima Drive
Ashland, MA 01721
(508) 881-7100
(508) 881-7105 FAX
1-800-287-5252 MA ONLY

CLEANROOM 4 CERTIFICATION REPORT : PARTICLE COUNTS / AIRFLOW PROFILES
PRESSURE DIFFERENTIALS
TEMPERATURE / RELATIVE HUMIDITY
AIR CHANGES PER HOUR



CLEANROOM	GOWNING
TOTAL SUPPLY CFM :	845
ROOM VOLUME :	2,570 FT ³
AIR CHGES / HR :	20
TOTAL EXHAUST CFM :	170
TOTAL RETURN CFM :	100

PRESSURE DIFFERENTIALS : CLEANROOM 4 > GOWNING 4 - .030 POS
GOWNING 4 > AMBIENT - .018 POS
CLEANROOM 4 > AMBIENT - .048 POS

PARTICLES MEASURED AT AND RECORDED IN CUBIC METERS OF AIR
AND CUBIC FEET OF AIR IN ACCORDANCE WITH ISO STANDARD 14644-1.

CLEANROOM 4 CERTIFIED AS ISO CLASS 6. GOWNING 4 CERTIFIED AS ISO CLASS 7.
CLASS 6 LIMITS: CUBIC FEET - 1,000 / CUBIC METERS - 35,200
CLASS 7 LIMITS: CUBIC FEET - 10,000 / CUBIC METERS - 352,000

Exhibit B

The Commonwealth of Massachusetts
 Executive Office of Health and Human Services
 Department of Public Health
 Division of Health Professions Licensure
 239 Causeway Street, Suite 400
 Boston, MA 02114
 Office of Public Protection

WHOLESALER INSPECTION REPORT

INVESTIGATOR J. Emery INSPECTION DATE 2/18/10

Corporation name Alatus

DBA name

Address 687 Waverly St

City / Town Framingham Zip 01702

Telephone 508 656-6480 Facsimile 508 - 879 - 7853

Hours of Operation M - F 8-5 Sat: / Sun: /

Name of Representative Participating in Inspection Patrick Foster

Schedule II Schedule III Schedule IV Schedule V Schedule VI

Board of Pharmacy Wholesale Distributor License No. Pending Exp. Date _____

DPH - DCP Controlled Substance Registration No. Enclosed Exp. Date _____

EA Registration No. Enclosed Exp. Date _____

ADMINISTRATION

YES NO COMMENTS

A. List of all officers, directors, managers and employees available listing each of their positions/duties? / _____

B. Current licenses displayed? / _____

C. Written policies and procedures on prescription drugs including directives on the following:

1. Procedure to identify/record/report losses or thefts? / _____

2. Procedure to correct errors on wholesaler's inventory? / _____

3. Procedure requiring oldest stock to be distributed first? / _____

4. Procedure on recall/withdrawal / _____

a) Requests by FDA, federal agency, Board? / _____

b) Voluntary actions by manufacturer?

5. Operation in event of strike, fire, flood or other disaster?

6. Procedure to assure outdated drugs separated/disposed of?

a) Maintenance of written records on prescriptive drugs destroyed or otherwise disposed of?

7. Policy/procedure on shipping/delivery of prescription drugs?

D. Do the personnel policies/practices meet the requirements of:

1. Screening all employees w/access to prescription drugs (schedule VI / non-federally controlled substances) education, and experience, conviction/dependency problems?
2. Screening employees w/access to federally controlled substances (schedules II-V) past conviction/dependency problems?

RECORDS

A. Maintains records of receipts/dispositions of each prescription drug, including at least:

1. Supplier of drug?
2. Address from where shipped?
3. Identity/quantity received?
4. Identity/quantity distributed?
5. Date of receipt?
6. Date of distribution?
7. Are records kept for two (2) years?
8. Type of records maintained:

Computer Hard Copy Immediately Available

STORAGE/SHIPPING

YES NO COMMENTS

A. Does facility meet general requirements? _____

1. Storage area facilitates access to prescription drugs? _____
2. Area maintained in a clean and orderly condition? _____
3. Area free of insects, rodents, birds or vermin? _____ *Contract monthly*

B. Do storage conditions comply with US Pharmacopoeia? _____

1. Temperature/humidity record maintained (59-86°F)? _____

C. Separation/disposal of prescription drugs:

1. Separate area specified for storage of outdated/damaged/adulterated drugs? _____
2. Are returned drugs sold to other purchasers?
 - a) If so, has examination/testing assured drugs not expired/adulterated? _____
3. Outdated/mislabeled/adulterated drugs in stock? _____

D. Examination of prescription drugs in shipment:

1. Incoming shipments examined for damage/contamination? _____
2. Outgoing shipments examined for damage/contamination? _____

E. Do vehicles used for transportation of prescription drugs meet cleanliness, temperature and security standards? _____ *FedEx*

SECURITY

YES NO COMMENTS

- A. Access to the drug storage area at a minimum/ well controlled? _____
- B. Outside perimeter properly lighted? _____
- C. Secure against access by unauthorized persons? _____
- D. Access to controlled substances area limited to authorized persons and equipped w/alarm system to detect entry? _____ *ADT*

E. Has this wholesaler been the subject of an investigation or been sanctioned by any licensing board for a federal or state regulatory agency?

YES _____ NO

If yes, please describe:

F. What training has the Designated Representative received? How long has he/she been employed?

REMARKS

I have participated in an inspection and have reviewed the Inspection Report with the Investigator:

Print Name PATRICK FOSTER Signature Patrick Foster

Title Dir. Process & Analytical Dev. License No. Pending

Investigator J. Loney Date 3/18/10